

Application No. 09/227,749  
Response dated November 11, 2003  
Reply to Office Action of July 11, 2003

### **REJECTION OF CLAIMS**

#### **Rejection of Claims 31-38 under 35 U.S.C. 112, first paragraph**

The claims are rejected on the grounds that Applicants have not shown that the claimed treatment is effective in treating Alzheimer's Disease. This rejection is traversed on the grounds that follow:

Attached is an abstract of M. Loeb et al., A Randomized Control Trial of Doxycycline and Rifampin for Patients with Alzheimer's Disease, submitted as a poster abstract for the annual meeting of the Infectious Disease Society of America (IDSA) on October 9-12, 2003. The abstract was downloaded, as abstract number 516 of page 108 of the meeting program, from the web site for the meeting (<http://www.idsociety.org/me/am2003/toc.htm>).

Loeb et al studied the effect of doxycycline and rifampin on patients with mild to moderate Alzheimer's Disease. The effect on performance in a test of cognitive ability was measured. There was a "significant" positive effect of antibiotic treatment when tests were taken at 6 months. Positive effects were also seen after 12 months. As a result, the study of Loeb et al. shows, with a reasonable degree of confidence, that antimicrobial agents are effective in treating Alzheimer's disease.

Loeb et al. also concluded that the mechanism is unlikely to be due to the effect of the antibiotics on Chlamydia. Whether their conclusion as to mechanism disagrees with that of the Applicants in any way is, however, irrelevant. It is not required that an Applicant understand the mechanism of his or her invention in order to obtain a patent on it.

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**Rejection of Claims 31-38 under 35 U.S.C. 103(a) as being unpatentable over Shor *et al* (US patent No. 5,424,187) in combination with Koskiemi *et al* (Eur Neurol 1996; 36:160-163)**

The claims are rejected on the grounds that: (1) Shor *et al* disclose the use of an antibiotic (optionally with an anti-inflammatory agent) for the treatment of Chlamydia; and (2) Koskiemi *et al* disclose that Chlamydia infections are associated with the CNS. This rejection is traversed for the reasons that follow.

Claims 31-38 are directed at the treatment of Alzheimer's disease. The prior art cited by the Examiner does not render Applicant's claimed inventions obvious because (1) Alzheimer's disease is not one the CNS diseases disclosed in Koskiemi *et al* and (2) at most, Koskiemi *et al* alert the reader that, if there is a diagnosis of a CNS infection, then Chlamydia should be considered as either the infectious agent or an associated infectious agent (See, for example the abstract). However, Alzheimer's Disease was not considered in the prior art to be an infectious disease. Therefore Koskiemi *et al* provided no motivation to use an antimicrobial agent in a patient with Alzheimer's disease.

In view of the foregoing, allowance of all claims is requested.

Respectfully submitted,

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